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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,181	07/11/2001	Michael W. Leviten	R-456	1164

7590 11/07/2003

DELTAGEN, INC.  
1003 Hamilton Avenue  
Menlo Park, CA 94025

EXAMINER

PARAS JR, PETER

ART UNIT PAPER NUMBER

1632

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/904,181	LEVITEN, MICHAEL W.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Peter Paras, Jr.	1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Applicant's amendment received on 7/9/03 has been entered. Claims 26, 31 and 34 have been amended. Claims 1-4, 11, 13-16, 21-25 and 37-40 have been cancelled. Claims 26-36 are pending and are under consideration.

It is noted that the amendment received on 7/9/03 is not in compliance with Rule 1.121. The amendment is not in compliance because claims 1-4, 11, 13-16, and 21-25 were indicated as withdrawn in the claims listing but were actually cancelled. However, this minor oversight did not preclude examination of the claims.

#### ***Sequence Compliance***

The instant application is now in sequence compliance.

#### ***Drawings***

Substitute Fig. 2A is approved.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26-36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The previous rejection is maintained for the reasons of record advanced on pages 3-6 of the Office action mailed on 3/7/03.

Applicant's arguments filed 7/9/03 have been fully considered but they are not persuasive. Applicants have asserted that the claimed transgenic mice have a specific and credible utility. Applicants further assert that one of ordinary skill in the art would conclude that antagonizing or decreasing expression of a sequence comprising the nucleotide sequence set forth in SEQ ID NO: 1 ameliorates a symptom associated with schizophrenia. Applicants submit that the instantly claimed mice could be used for screening agents intended to treat schizophrenia or affect prepulse inhibition. See 5-7 of the amendment.

In response, the Examiner maintains the instantly claimed transgenic mouse lacks credible or well-established utility. In particular, it is maintained the evidence of record does not provide a correlation between increased prepulse inhibition and any disease or disorder. The specification has asserted that increased prepulse inhibition is opposite to the deficit observed in schizophrenia patients. Paylor et al (see pages 5-6 of Office action mailed on 3/7/03) supports such assertions but however does not provide a correlation between increased prepulse inhibition and any disease or disorder. Moreover, while the specification has purported that the nucleotide sequence set forth in SEQ ID NO: 1 encodes a ubiquitin-specific protease (see page 6), the evidence of record has failed to provide a correlation between any ubiquitin-specific protease related disease/disorder and increased prepulse inhibition. The specification has merely provided general assertions that the claimed transgenic mice may be used to identify agents that affect a phenotype related to the mice. As such it appears that applicant's assertions regarding utility of the claimed transgenic mouse for screening agents that

could treat schizophrenia are unsupported by the evidence of record. No evidence has been prevented, which correlates the phenotype exhibited by the claimed transgenic mouse, increased prepulse inhibition, and schizophrenia; the evidence of record including the specification, in fact has reported that increased prepulse inhibition is the opposite of the deficit observed in schizophrenia patients. Accordingly, it is maintained that the asserted utility of the instantly claimed transgenic mouse is neither credible nor well established.

Thus, the previous rejection is maintained for the reasons of record.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The previous rejection is maintained for the reasons of record as it is maintained that the instant specification has not taught how to use the claimed transgenic mouse. See the preceding utility rejection and also the previous Office action mailed on 3/7/03.

The other rejections of the claims under 35 U.S.C. 112, 1<sup>st</sup> paragraph have been withdrawn in view of the amendments to the claims.

### **Conclusion**

**No claim is allowed.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.  
Art Unit 1632

**PETER PARAS**  
**PATENT EXAMINER**

A handwritten signature in black ink, appearing to read "Pete Paras", written in a cursive style.